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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,222	09/01/2006	Chikara Murakata	P28672	8988

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EXAMINER	
HAVLIN, ROBERT H	

ART UNIT	PAPER NUMBER
1626	

NOTIFICATION DATE	DELIVERY MODE
03/03/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/553,222	MURAKATA ET AL.	
	Examiner	Art Unit	
	ROBERT HAVLIN	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-40* is/are pending in the application.

4a) Of the above claim(s) *30,33 and 35-40* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29,31,32 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

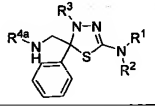
Status of the claims: Claims 1-23, and 26 were cancelled. Claims 29-40 were added and are now pending.

Priority: This application is a 371 of PCT/JP04/05489 (04/16/2004) and claims foreign priority to JAPAN 2003-114071 (04/18/2003) and JAPAN 2003-164727 (10/06/2003).

Election/Restrictions

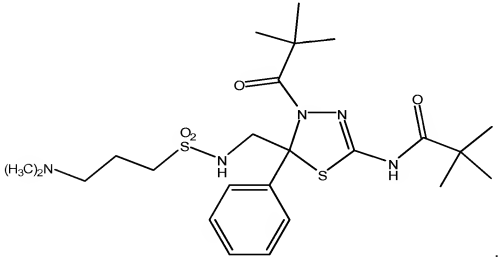
Applicant previously elected Group I (claims 13-23) and the species of compound No. 237 allegedly reading on claims 13-19, 22, and 23 with the following structure:

Table 13 (Continued)



Example No.	Compound No.	R^1	R^2	R^3	R^{4a}
42	237	H	$COC(CH_3)_3$	$COC(CH_3)_3$	$SO_2(CH_2)_3N(CH_3)_2$

Redrawn as:



As detailed in the following rejections, the generic claim encompassing the elected species was not found patentable. Therefore, the provisional election of species is given effect, the examination is restricted to the elected species only, and claims not reading on the elected species are held withdrawn. Accordingly, claims 30, 33, and 35-40 are hereby withdrawn.

Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection through amendment, the amended Markush-type claim will be reexamined to the extent necessary to determine patentability of the Markush-type claim. See MPEP 803.02.

1. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

RESPONSE TO APPLICANT REMARKS

All claims were cancelled, therefore the grounds of rejection in the prior office action are rendered moot and hereby withdrawn.

NEW CLAIM REJECTIONS NECESSITATED BY AMENDMENT

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

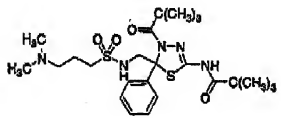
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 29, 31, 32, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Murakata et al. (WO 03/051854, cited in the IDS in Japanese, abstract from CAPLUS Accession # 2003:491200, and English Language equivalent PGPUB US 20060074113) in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51).

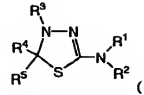
The instant claims include a compound with the following formula useful as an antitumor agent:



(237) which is the elected species.

Determining the scope and contents of the prior art

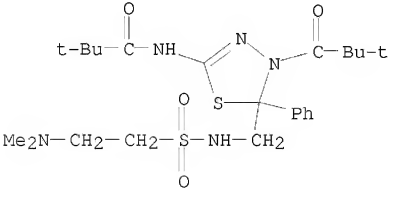
Murakata et al. teaches a genus of compounds of formula (I) as antitumor agents:



(I)

(57) Abstract: An antitumor agent which contains as an active ingredient a thiadiazoline derivative represented by the following general formula (I): [wherein R^1 and R^4 are the same or different and each represents hydrogen, (un)substituted lower alkyl, (un)substituted lower alkynyl, (un)substituted lower alkenyl, etc.; R^3 represents an (un)substituted heterocyclic group, (un)substituted aryl, etc.; R^2 represents $-C(=W)R^A$, etc.; and R^5 represents hydrogen, $-C(=W^A)R^{AA}$, etc.] or a pharmacologically acceptable salt of the derivative.

The prior art also teaches the following compound:



This compound is described as being an antitumor agent and is referred to as example 167 in table 8.

Silverman teaches drug discovery, design, and development through modifications of the structure of known molecules showing some activity. For example, Silverman teaches on pages 16-18 homologation of carbon chains. Specifically, the method teaches how lengthening a carbon chain (by increasing successive CH2 groups) increases pharmacological effects.

Ascertaining the differences between the prior art and the claims at issue

The difference between the Murakata compound and the claims is an additional CH2 group on the sulfonamide group.

Resolving the level of ordinary skill in the pertinent art.

One of ordinary skill in the art of pharmaceutical development would be well versed in the teachings of references such as Silverman. One of ordinary skill in the art would consider routine and well within their technical grasp the process of altering the structure of drug molecules and screen them for activity on a large scale to assess potency.

Considering objective evidence present in the application indicating nonobviousness

The record contains no evidence of secondary considerations indicating the claims are nonobvious.

Upon reading the teachings of Murakata, one of ordinary skill in the art would immediately recognize potential to improve the potency of the compounds taught therein through altering structural elements via homologation. Silverman specifically teaches the homologation methodology and provides the underlying physicochemical motivation of altering the lipophilicity of the molecule which would reasonably be applicable to the compound of Murakata. In addition, the Murakata compound is a homolog of the instant claims, only differing by successive addition of –CH2- group, thus one of ordinary skill in the art would expect the physical properties of the two compounds to be similar.

In Eisai Co. Ltd. v. Dr. Reddy's Laboratories Ltd., 87 USPQ2d 1452, 1454 (Fed. Cir. 2008), the Federal Circuit clarified the proof of obviousness in structural similarity situations such as this:

> Where, as here, the patent at issue claims a chemical compound, the analysis of the third Graham factor (the differences between the claimed invention and the prior art) often turns on the structural similarities and differences between the claimed compound and the prior art compounds. See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 471 F.3d 1369, 1377 [81 USPQ2d 1324] (Fed. Cir. 2006) (noting that, for a chemical compound, a prima facie case of obviousness requires "structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed compositions" (quoting In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990) (en banc))). Obviousness based on structural similarity thus can be proved by identification of some motivation that would have led one of ordinary skill in the art to select and then modify a known compound (i.e. a lead compound) in a particular way to achieve the claimed compound. See Takeda Chem. Indus. v. Alphapharm Pty., Ltd., 492 F.3d 1350, 1356 [83 USPQ2d 1169] (Fed. Cir. 2007). In keeping with the flexible nature of the obviousness inquiry, KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 1739 [82 USPQ2d 1385] (2007), the requisite motivation can come from any number of sources and need not necessarily be explicit in the art. See Aventis Pharma Deutschland GmbH v. Lupin, Ltd., 499 F.3d 1293, 1301 [84 USPQ2d 1198] (Fed. Cir. 2007). Rather "it is sufficient to show that the claimed and prior art compounds possess a 'sufficiently close relationship ... to create an expectation,' in light of the totality of the prior art, that the new compound will have 'similar properties' to the old." Id. (quoting Dillon, 919 F.2d at 692).

This is further supported by caselaw and the MPEP in section 2144.09(II):

> Compounds which are position isomers (compounds having the same radicals in physically different positions on the same nucleus) or homologs (compounds differing regularly by the successive addition of the same chemical group, e.g., by -CH2- groups) are generally of sufficiently close structural similarity that there is a presumed expectation that such compounds possess similar properties. In re Wilder, 563 F.2d 457, 195 USPQ 426 (CCPA 1977); see also In re May, 574 F.2d 1082, 197 USPQ 601 (CCPA 1978).

Therefore, because the reference teaches homologs of the instantly claimed compounds and the MPEP states that homologs are presumed to possess similar

properties, it would have been obvious to one of ordinary skill in the art to modify the alkyl chain length and arrive at the instant invention.

One of ordinary skill in the art would have been guided by the prior art to make the invention as claimed because Murakata teaches the homologous compound, while Silverman teach how to modify the compound to arrive at the instant invention. Therefore, the claims are obvious.

Double Patenting

5. Claims 13-17 and 22-23 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 7,425,636 in view of Silverman, R. B. (The Org. Chem. of Drug Design and Drug Action, Academic Press, Inc.: San Diego, 1992, pp. 4-51). Although the conflicting claims are not identical, they are not patentably distinct from each other because the '636 patent claims overlapping subject matter and teaches species that are the same as those referred to in the above 103 rejection, specifically example 167 in table 8, cols. 35-36. Thus, the 103 rejection above is incorporated by reference.

Conclusion

The claims are not in condition for allowance. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT HAVLIN whose telephone number is (571)272-9066. The examiner can normally be reached on Mon. - Fri., 7:30am-5pm EST.

If attempts to reach the examiner by telephone are unsuccessful the examiner's supervisor, Joe McKane can be reached at (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert Havlin/
Examiner, Art Unit 1626

/Rebecca L Anderson/
Primary Examiner, Art Unit 1626